

### **REMARKS**

Reconsideration of the rejection of all claims is respectfully requested in view of the above amendments and the following remarks.

#### ***Specification Amendments***

The specification has been amended in a manner consistent with amendments to claim 1 to address grounds 1 and 2 at page 11 of the Action with respect to the rejection under 35 U.S.C. 112, second paragraph. In particular, the structure of formula (IC) at specification page 3 has been replaced with the same structure except it is now clear that a tricyclic ring is not depicted. Secondly, in the text following formula (IE) the definition of the substituent R<sup>5</sup> has been deleted inasmuch as there is no R<sup>5</sup> substituent in formula (IE).

The specification has also been amended at page 23, lines 6-9 to identify US Patent 6,908,920 as corresponding to WO 02/04429, already cited in the specification with respect to the SRB assay noted a page 23, lines 14-15. US Patent 6,908,920 issued from the US National Stage of PCT /GB01/03084, which published as WO 02/04429.

Clearly no new matter has been added by these amendments, and entry of the above specification amendments is believed to be in order and is respectfully requested.

#### ***Claim Amendments***

Claims 18-20 and 34 and 36-38 have been newly cancelled herein (claims 22-32 having previously been cancelled), claim 33 has been retained as previously presented and claims 1-17, 21 and 35 have been amended in the manner noted below:

**Claim 1** has been amended so such that each limitation now recited therein is fully supported by the original priority application GB 0205693.5 filed March 9, 2002. In particular, the replacement definition of R<sup>1</sup> with respect to the compound of formula (IA) is found at specification page 7, lines 15-21 and the replacement definition of R<sup>1</sup> with respect to the compound of formula (IB) is found at specification page 7, lines 26-29. Certain of the other definitions have been narrowed in scope to bring this claim fully within the scope of the priority application. The structure of formula (IC) has been opened up to be clear that a tricyclic ring is not present, and the definition of R<sup>5</sup> with respect to compounds of formula

(IE) has been removed in that there is no  $R^5$  in this formula. Also, all reference to compounds of formula (IG) has been removed from this claim in that such compounds were not present in the priority application.

**Claim 2** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 3** has been amended to be dependent on claim 2.

**Claim 4** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 5** has been amended to be dependent on claim 4, and to delete compounds that were not specifically named or exemplified in the priority application.

**Claim 6** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 7** has been amended to remove various groups from the definition of  $R^1$  in that they were not explicitly recited in the priority application. This particular selection is found in the priority application and also in the present specification at page 11, lines 1 to 3.

**Claim 8** has been amended to be dependent on claim 6, and to delete compounds that were not specifically named or exemplified in the priority application.

**Claim 9** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 10** has been amended to remove various groups from the definitions of  $R^1$  and  $R^3$  in that they were not explicitly recited in the priority application. Basis for this particular selection is found in the priority application and also in the present specification at page 12, lines 12, 16 and 17.

**Claim 11** has been amended to be dependent on claim 9, and to delete one compound that was not specifically named or exemplified in the priority application.

**Claim 12** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 13** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 14** has been amended to be dependent on claim 12.

**Claim 15** has been amended only with regard to a formality, and the scope of this claim remains the same.

**Claim 16** has been amended to remove various groups from the definitions of  $R^1$  and  $R^3$  in that they were not explicitly recited in the priority application. Basis for this particular selection is found in the priority application and also in the present specification at page 13, lines 25, 30 and 31, and at page 14, lines 1 and 2.

**Claim 17** has been amended to be dependent on claim 15, and to delete two compounds that were not specifically named or exemplified in the priority application.

**Claims 18, 19 and 20** have been cancelled in that compounds of formula (IG) were not present in the priority application.

**Claim 21** has been amended to be dependent on claim 1.

**Claims 22-32** were previously cancelled in the Preliminary Amendment of September 9, 2004.

**Claim 33** has been maintained as previously presented.

**Claim 35** has been limited to a method for the treatment of rheumatoid arthritis in order to expedite the prosecution of this application to allowance, as discussed further below with respect to the rejection of method claims for non-enablement.

**Claims 34 and 36-38** have been cancelled in order to expedite the prosecution of this application to allowance, as discussed further below with respect to the rejection of method claims for non-enablement.

The above claim amendments are being made without abandonment or waiver of Applicants' right to prosecute any deleted subject matter in one or more continuing applications. It should be apparent from the above remarks that no new matter has been added by these amendments to the claims. Therefore, entry of these amendments is believed to be in order and is respectfully requested. Following entry of these amendments, claims 1-17, 21, 33 and 35 remain pending in this application.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

At page 2 of the Action, method of treatment claims 33-38 have been rejected under 35 USC § 112, 1<sup>st</sup> paragraph. The Examiner asserts that

... the specification, while being enabling for a method of treating rheumatoid arthritis, does not reasonably provide enablement for a method for producing a cell cycle inhibitory (anti-cell proliferation) effect; a method for the inhibition of CDK2, CDK4, or CDK6; a method for treating a disease or medical condition selected from cancer, fibroproliferative and differentiative disorders, psoriasis, Kaposi's sarcoma, etc.; or a method for preventing hair loss arising from the treatment of malignant conditions with pharmaceutical agents.

While not agreeing to this ground for rejection, method claims 34 and 36-38 have been cancelled and claim 35 has been amended in order to expedite the prosecution of this application to allowance. Specifically, claim 35 has been limited to the treatment of "rheumatoid arthritis," which the Examiner has indicated is enabled by the specification. However, applicant reserves the right to prosecute the removed method subject matter in one or more continuing applications.

Reconsideration of the rejection of method claim 33 is respectfully requested. Method claim 33 is directed toward a method for producing a cell cycle inhibitory (anti-cell-proliferation) effect in a warm-blooded animal, and finds direct support and enablement in the assay discussed at specification page 23, lines 6-15 and the SRB assay discussed therein and described in WO 02/04429 noted therein (corresponding to US Patent 6,908,920). It is submitted that this disclosure and assay sufficiently enable claim 33.

It is therefore believed that this section 112, paragraph 1 ground for rejection has been overcome by the above amendments and remarks, and withdrawal of this ground for rejection is respectfully requested.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

At page 11 of the Action, claims 1-21 and 33-38 have been rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for three enumerated reasons:

1. In claim 1, the Examiner notes that the structural formula (IC) appears to represent a tricyclic ring wherein the pyrimidine and the imidazole ring are fused together by a 6-membered ring with  $R^2$  as a ring member. A redrawn formula (IC) has been inserted in above-amended claim 1 which has been opened up to be clear that a tricyclic ring is not present. For consistency, this same amendment has been made above to formula (IC) in the specification at page 3.

2. In claim 1, the Examiner notes that following formula (IE), a definition is provided for the substituent " $R^5$ ", but that the structural formula does not show the presence such substituent. Claim 1 has been amended to remove the definition of  $R^5$  in the text following formula (IE). For consistency, this same amendment has been made above to the corresponding passage regarding formula (IE) at pages 4 and 5 of the specification.

3. The Examiner further notes that claims 3, 5, 8, 11, 14, 17 and 20 recite "A compound of formula ...", but these claims do not contain the structural formula recited in the claim. It is believed that this ground for rejection has been overcome by the above amendments, by which:

Claim 3 has been made dependent on claim 2;

Claim 5 has been made dependent on claim 4;

Claim 8 has been made dependent on claim 6;

Claim 11 has been made dependent on claim 9;

Claim 14 has been made dependent on claim 12;

Claim 17 has been made dependent on claim 15; and

Claim 20 has been cancelled.

It is believed that each of the section 112, paragraph 2 grounds for rejection has been overcome by the above amendments, and withdrawal of this ground for rejection is respectfully requested.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-21 and 33-38 have been rejected under 35 U.S.C. 103(a) as being obvious over Breault *et al.*, WO 02/20512 (hereinafter "WO '512"), which the Examiner notes was published March 14, 2002. The reference is said to generically teach imidazolo-5-yl-2-

anilino-pyrimidine compounds having cell cycle inhibitory activity, pointing specifically to formula (I) on page 2 of the reference and the compounds of the Examples.

This reference is first apparently applied under §102(a)/ §103(a) inasmuch as the March 14, 2002 publication date is *less than one year* before the March 3, 2003 filing date of the International Application of which the present application is the U.S. National Stage. However, the Examiner notes that WO '512 was published March 14, 2002, which is *after* the March 9, 2002 priority date claimed for this application, but justifies this §102(a)/ §103(a) based rejection on the assertion that the foreign priority document does not fully support the present claims. It is respectfully submitted, as discussed above, that the above amendments now bring each element of each claim within the scope of the March 9, 2002 priority document, thereby giving all claims the benefit of the earlier filing date of the priority document. Therefore, this §102(a)/ §103(a) based rejection over WO '512 has been obviated.

This reference is also applied to a rejection based on §102(e)/ §103(a). However, the subject matter of WO '512 and the presently claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Therefore, the present claims fall within the §103(c) exception whereby WO '512 is not prior art to the present claims under §102(e).

It is therefore respectfully submitted that WO '512 is not prior art to the present claims under either §102(a) or §102(e), and therefore this obviousness rejection under §102(a)/ §103(a) and §102(e)/ §103(a) should be withdrawn.

***Claim Rejections - Obviousness-Type Double Patenting over US 6,969,714***

At page 17 of the Action, claims 1-21 and 33-38 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,969,714 (herein after the '714" Patent"), which issued from the US National Stage application of the PCT application that published as WO '512 discussed above. The Examiner notes that although the conflicting claims are not identical, they are asserted not to be patentably distinct from each other because the instantly claimed compounds are

structurally analogous to the reference compounds for the reasons summarized above with respect to the rejection under 35 U.S.C. 103.

In order to expedite prosecution of this application to allowance, a Terminal Disclaimer is submitted herewith with respect to the '714 Patent. This Terminal Disclaimer is being submitted with the understanding that the filing thereof is not intended to be, and does not constitute, an admission that an obviousness-type double patenting rejection would be proper between the claims of the '714 Patent and the presently claimed invention (*see* MPEP 804.02II).

***Provisional Obviousness-Type Double Patenting over  
Coping Applications No. 10/507,163 and No. 10/507,169***

Claims 1-21 and 33-38 have been *provisionally* rejected for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/507,163, and also over claims 1-20 of copending Application No. 10/507,169. Both of these applications are currently pending before Examiner Rao with no allowed claims. A response to the May 18, 2007 non-final rejection is currently under preparation.

Accordingly these provisional rejections remain provisional, and Applicant is not able to meaningfully address the rejections unless and until the claims are fixed in these application by allowance. Therefore, when the *provisional* obviousness-type double patenting rejection is the only remaining ground for rejection in this application (which it is believed should be the case following this Amendment and Response), then the present application should be allowed to issue.

***Information Disclosure Statement***

The Examiner's attention is respectfully called to the Supplemental Information Disclosure Statement being filed with this response.

Applicants also wish to bring to the Examiner's attention the current status of the following technically related applications of Applicants' assignee:

**US Application 10/507,162** is currently pending before Examiner Deepak R. Rao, and a final Action rejecting all claims was mailed on November 13, 2007.

**US Application 10/507,163** is currently pending before Examiner Deepak R. Rao, and a non-final Action rejecting all claims was mailed on May 18, 2007 and a response is currently under preparation. This application has been cited in a provisional obviousness-type double patenting rejection in the present application, as discussed above.

**US Application 10/507,169** is currently pending before Examiner Deepak R. Rao, and a non-final Action rejecting all claims was mailed on May 18, 2007 and a response is currently under preparation. This application has been cited in a provisional obviousness-type double patenting rejection in the present application, as discussed above.

**US Application 10/556,561** is currently pending before Examiner Venkataraman Balasubramanian, and a response to a non-final Action was filed October 23, 2007.

**US Application 10/556,607** has been assigned to Examiner Deepak R. Rao, and a first Action is predicted to be mailed in 5 months from the present date.

**US Application 10/586,954** has been assigned to Examiner Deepak R. Rao, and a first Action is predicted to be mailed in 9 months from the present date.

**US Application 11/793,254** is still undergoing preexam processing and has not yet been assigned to a Group Art Unit or to an Examiner, and no prediction is available as of yet as to when a first Action might be mailed.

**US Application 11/817,389** is still undergoing preexam processing and has not yet been assigned to a Group Art Unit or to an Examiner, and no prediction is available as of yet as to when a first Action might be mailed.

It is understood that the Examiner has full electronic access to each of these files. However, the undersigned would be happy to provide the Examiner with paper copies of any documents in these files upon requested, rather than inundating the US PTO and the Examiner at this time with unwanted paper.

### ***Conclusion***

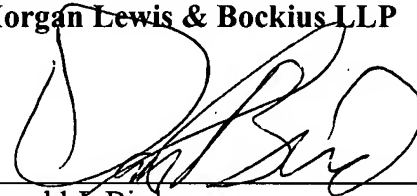
All ground for rejection having been addressed and, it is believed overcome, by the foregoing Amendments and Remarks, the allowance of all claims is respectfully requested together with the mailing of a Notice to that effect. However, if any issues remain outstanding



after consideration of the above, it is respectfully requested that the Examiner telephone the undersigned to explore whether an expedited resolution might be obtained.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**



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